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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,683	06/24/1999	GREGOR CEVC	2001377.123 US1	2670

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WILMER CUTLER PICKERING HALE AND DORR LLP  
399 PARK AVENUE  
NEW YORK, NY 10022

EXAMINER
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KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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08/17/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

teresa.carvalho@wilmerhale.com  
tina.dougal@wilmerhale.com  
michael.mathewson@wilmerhale.com

## Office Action Summary

Application No.

09/284,683

Applicant(s)

CEVC, GREGOR

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 106-110 and 112-121 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 106-110 and 112-121 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7-12-07
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment dated 7-12-07 is acknowledged.

Claims included in the prosecution are 106-110 and 112-121.

In view of the amendments, the 112, rejection, 102 rejections over Lichtenberger and Ghyczy and the 103 rejections involving these references are withdrawn.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 106-110 and 112-121 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 106 recites the language 'consisting essentially of'; however, claim also recites 'one or more stabilizers'. It is unclear as to what these stabilizers are and what they stabilize. That is, whether the vesicle or the active agent. Instant specification on page 19 names three compounds, phenol, cresol and benzyl alcohol followed by the expression, 'etc'. Dependent claim 116 recites once again 'consisting essentially of' followed by 'antioxidants'. Since antioxidants prevent the oxidation of the phosphatidylcholine and also oxidizable active agents, one can consider the antioxidants as stabilizers. Claim language is confusing.

Furthermore, according line 2 of claim 106, the transport is through mucous membranes; it is unclear as to how one can transport through mucous membranes when the administration is to the skin.

*Claim Rejections - 35 U.S.C. § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 106-110, 114-118 and 121 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheffield (4,937,254) of record.

Sheffield teaches a method of administration of liposomal formulations containing phosphatidylcholine and NSAID. The method of administration is topically and either internally or externally which implies skin. The composition further contains PBS and hydrocolloids (col. 3, lines 7-56; col. 6, line 15 through col. 7, line 12, Examples 13-15).

5. Claims 106-110, 112-113, 116-118 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayward (5,585,109).

Hayward discloses liposomal formulations containing soy lecithin and salicylic acid and a method of delivery to the skin. The carrier material is polymethacrylate gel.

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The pH is 6.5 to 7.5. The composition further contains antioxidants and preservatives and hydrocolloids (columns 3-7).

*Claim Rejections - 35 U.S.C. § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 106-110, 112-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayward (5,585,109) or Sheffield (4,937,254) in combination with Unger (5,209,720).

Hayward discloses liposomal formulations containing soy lecithin and salicylic acid and a method of delivery to the skin. The carrier material is polymethacrylate gel. The pH is 6.5 to 7.5. The composition further contains antioxidants and preservatives

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and hydrocolloids (columns 3-7). What is lacking in Hayward is the use of claimed antioxidants and Stabilizers.

Sheffield teaches a method of administration of liposomal formulations containing phosphatidylcholine and NSAID. The method of administration is topically and either internally or externally which implies skin. The composition further contains PBS and hydrocolloids (col. 3, lines 7-56; col. 6, line 15 through col. 7, line 12, Examples 13-15).

Unger while disclosing liposomal compositions teaches that to prevent bacterial degradation on storage bacteriostatic agents such as benzyl alcohol should be added. Unger also teaches that to prevent the oxidation of lipids, antioxidants such as tocopherol and ascorbic acid should be added (abstract, col. 7, lines 1-11).

The addition of antioxidants and stabilizers in the compositions of Hayward or Sheffield would have been obvious to one of ordinary skill in the art since such an addition would prevent oxidation of lipids and degradation by bacteria respectively as taught by Unger. What is lacking in Hayward is the teaching of the use of synthetic phospholipid. However, since liposomes can be formed with either natural or synthetic phospholipids, it is deemed obvious to one of ordinary skill in the art to choose the desired source with a reasonable expectation of success. Hayward and Sheffield also lack the teaching of the application of the claimed amount of the liposomes on the skin surface. However, since the amount applied depends upon the condition to be treated and the severity of the condition, it is deemed obvious to one of ordinary skill in the art to manipulate this parameter to obtain the best possible results.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that none of the references disclose vesicles comprising, missing less consisting essentially of, one or more stabilizers and a method for transporting an NSAID through the skin or mucous membrane, comprising administering a vesicle that consists essentially of one or more phosphatidylcholines, a salt of one or more NSAIDs and one or more stabilizers. This argument is not persuasive. Hayward teaches the topical administration of Salicylic acid in liposomes containing lecithin (phosphatidylcholine). Instant claim 106 recites 'one or more stabilizers' without stating what these stabilizers are. In such a case, the compounds such as arginine taught by Hayward can be construed as stabilizers. Applicant's arguments regarding Unger that he discloses methods for inducing ultrasonic hyperthermia comprising intravasularly and by other modes of gas-filled liposomes are not persuasive since this reference is combined for its teachings of the advantages of adding compounds such as benzyl alcohol to the liposomes (prevent the bacterial degradation of liposomes) and this advantage would be the same irrespective of what the liposomes are used for and what they encapsulate. Although Hayward does not teach the encapsulation of other NSAIDs, it would have been obvious to one of ordinary skill in the art to encapsulate any NSAID with a reasonable expectation of success.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK